K110099

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JUN 29 2011

CooperVision™

CooperVision: 510(k) Summary (as required by section 807.92(c)).
K110099

Submitted By: CooperVision Inc.
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588

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Regulatory Affairs
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Date Prepared: May 26 2011

Trade Name: Proclear Toric XR (omafilcon A) Soft (hydrophilic) Contact Lens
Proclear Multifocal XR (omafilcon A) Soft (hydrophilic) Contact Lens
Proclear Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lens

Common Name: Soft Contact Lens

Classification: Lenses, Soft Contact, Daily Wear
Class II: LPL, 21 CFR 886.5925

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510(k) Summary

Proclear Toric XR, Multifocal and Multifocal XR
Daily Wear Soft Contact Lenses

Substantially Equivalent Devices:

Proclear Toric XR, Proclear Multifocal XR and Proclear Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear, K081865.

Proclear XC and Proclear 1 day (omafilcon A) Hydrophilic Contact Lenses for Daily Wear, K061948.

Device Description:

The Proclear Toric XR, Multifocal XR and Multifocal Toric (omafilcon A) Contact Lenses are made from a material containing 59% water and 41% omafilcon A, a polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with Vat Blue 6.

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lens is a back surface toric.

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as a multifocal lens with an aspherical front surface and spherical back surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. The Proclear Multifocal XR is designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lens front surface is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic.

Indication for Use:

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes that are myopic or hyperopic in powers from -20.00 to +20.00, possess astigmatism to -5.75 diopters or less, and are presbyopic. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes in powers from -20.00 to +20.00 that are myopic or hyperopic and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

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510(k) Summary

Proclear Toric XR, Multifocal and Multifocal XR Daily Wear Soft Contact Lenses

Indication for Use (continued)

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic in powers from -20.00 to +20.00 diopters and astigmatism corrections to -5.75 diopters. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non- Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by the eye care practitioner in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

Technological Characteristics

The technological characteristics of the subject lens and the predicate lenses are compared in the following tables. The Subject device has the same technological characteristics (i.e., design, material, package, parameters) as the predicate devices.

Material Comparison

	Subject Device	**Predicate Device**	**Predicate Device**
Product name	Proclear Toric XR Proclear Multifocal XR Proclear Multifocal Toric	Proclear Toric XR Proclear Multifocal XR Proclear Multifocal Toric	Proclear XC Proclear 1 day
Material USAN Name	Omafilcon A	Omafilcon A	Omafilcon A
510(k) number	This submission	K081865	K061948
FDA Category (Group)	Group II Non-Ionic High Water	Group II Non-Ionic High Water	Group II Non-Ionic High Water
Manufacturing method	Finished Inside Polymerization System II	Finished Inside Polymerization System	Cast molded
Curing	Thermal Cure	UV Cure	Thermal cure
Sterilization	Moist Heat (steam) in validated Autoclave	Moist Heat (steam) in validated Autoclave	Moist Heat (steam) in validated Autoclave
Packaging	Blister Pack	Blister Pack	Blister Pack
Visibility tint	VAT Blue 6	VAT Blue 6	VAT Blue 6

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Proclear Toric XR, Multifocal and Multifocal XR Daily Wear Soft Contact Lenses

Parameter Comparison			
	Subject Device	**Predicate Device**	**Predicate Device**
Product name	Proclear Toric XR Proclear Multifocal XR Proclear Multifocal Toric	Proclear Toric XR Proclear Multifocal XR Proclear Multifocal Toric	Proclear XC Proclear 1 day
Water Content	59% ± 2%	59% ± 2%	60% ± 2%
Refractive Index	1.395 ± 0.005	1.40	1.40
Oxygen Permeability x 10^{-11}	21.05	21.05	21.00
Light Transmission	>90%	>90%	>90%
Base Curve	8.0 to .9.3 mm	8.0 to .9.3 mm	8.0 to .9.5 mm
Diameter	13.6 to 15.2 mm	13.6 to 15.2 mm	13.0 to 15.5 mm
Power	-20.00 to +20.00	-20.00 to +20.00	-20.00 to +20.00

Non-Clinical Testing A series of in-vitro and in-vivo preclincal toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

Test	Acceptance Criteria	Result
Cytotoxicity Test ISO 10993 – 5: 1999: Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity	All 3 monolayers exposed to the test article show no grade greater than grade 2 (reactivity mild)	Pass
ISO Ocular Irritation ISO 10993 – 10:2002: Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Hypersensitivity	Test extract shows no significant irritation over the reagent control during the observation period.	Pass
Systemic Toxicity Study ISO 10993 – 11: 1996: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.	During the observation period, none of the animals treated with the individual test extract exhibit a significantly greater reaction that the control animals.	Pass

Summary continued on next page

Proclear Toric XR, Multifocal and Multifocal XR Daily Wear Soft Contact Lenses

Non-Clinical Testing (continued)

Summary Results of Testing

Test	Acceptance Criteria	Result
ISO Contact Lens 22 Day Ocular Irritation Study ISO 9394 Ophthalmic Optics – Contact Lenses and Contact Lens Care Products - The determination of Biocompatibility by Ocular Study with Rabbit Eyes.	Scores from macroscopic and microscopic ocular examinations equivalent between test and control eyes.	Pass
Total Extractables , Water content, Dk, Light Transmittance, refractive index tested per ISO 18369-4:2006 Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials: section 4.2	Equivalent to predicate lens	Pass

The results for the non-clinical testing demonstrate:

- The lens material and lens material extracts are non-toxic, non-irritating under the experimental conditions.
- The lens physical and material properties are consistent with currently marketed soft contact lenses.
- No evidence of unsafe amounts of residue in the extractables.
- Physicochemical testing of the subject lenses demonstrated equivalency to the predicate devices.
- Lens remains sterile and stable in the package, for the established shelf life.

Clinical

The technical characteristics, manufacturing and sterilization process of the subject lens are equivalent to omafilcon A soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

Conclusion Drawn from Studies:

Validity of Scientific Data

Contract laboratories under Good Manufacturing Practice regulations conducted toxicological and microbiology studies.
Chemistry, shelf-life and leachablility studies were conducted by CooperVision and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the CooperVision (omafilcon A) Proclear Toric XR, Proclear Multifocal and Proclear Multifocal XR contact lens is as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the requested indications.

Risk and Benefits

The risks of the subject lens are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CooperVision Inc.
c/o Ms. Lisa Hahn
Global Regulatory Affairs Manager
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588

JUN 29 2011

Re: K110099
Trade/Device Name:
Proclear Toric XR (Omafilcon A) Soft (hydrophilic) Contact Lens
Proclear Multifocal XR (Omafilcon A) Soft (hydrophilic) Contact Lens
Proclear Multifocal Toric (Omafilcon A) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 27, 2011
Received: May 31, 2011

Dear Ms. Hahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Proclear Toric XR, Multifocal XR and Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear

Indications for Use:

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic in powers from -20.00 to 20.00, possess astigmatism to -5.75 diopters, and are presbyopic. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

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Prescription Use: **YES** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Please Do Not Write Below this line-Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110099